REMARKS

Claims 3-16 are pending in the application. Claims 6-11 are withdrawn from consideration. Claims 3-5 and 12-16 stand rejected. Claims 3 and 12 have been amended. Applicant now addresses the Examiner's comments and claim rejections in the order presented in the office action to the extent that they might be applied to amended Claims 3 and 12 and pending Claims 4, 5 and 13-16.

Restriction/election Requirement

In a previous office action, Claims 3-16 were subject to a restriction/election requirement, and a provisional election of Group I (Claims 3-5 and 12-16) was made by Applicant. Applicant confirms election of Group I (Claims 3-5 and 12-16) without prejudice. Applicant requests the remaining claims be withdrawn from consideration with reservation of rights to present in a divisional application.

Rejection under 35 U.S.C. §102

Claims 3-5 and 12-16 stand rejected under 35 U.S.C. §102(b) as anticipated by Edmundson et al. (U.S. Patent No. 5,654,334). The Examiner contends that Edmundson et al. discloses a method for decreasing pain in a patient (e.g., osteoarthritis patient) with aspartame and C2-6 esters of aspartylphenylalanine in an effective amount of about 80-320 mg (about 1-4 mg/kg body weight), and that although Edmundson et al. does not explicitly disclose treating for high whole blood viscosity or abnormally viscous whole blood in a patient, prior treating of patients with osteoarthritis, who may be associated with whole blood viscosity, would have had the necessary effect of also treating for high or abnormal viscous whole blood viscosity. Therefore, Claims 3-5 and 12-16 are considered anticipated by Edmundson et al. Applicant traverses this rejection as it applies to amended Claims 3 and 12 and pending Claims 4, 5 and 13-16.

In order for a reference to anticipate a claim, the reference must teach every element of the claim (MPEP 2131, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Applicant disagrees with the Examiner's conclusion

that Edmundson et al. anticipates amended Claims 3 and 12 and Claims 4, 5 and 13-16 because Edmundson et al. does not possess each and every element of the claims.

In the present specification, Applicant discloses that high whole blood viscosity is associated with various diseases such as multiple myeloma, primary or Waldenström's macroglobulinemia, heavy chain diseases which clinically mimic multiple myeloma, systemic lupus erythematosus, arthritis, and sickle cell disease (Page 1, line 14-23). Example 1 of the present specification gives evidence of reducing whole blood viscosity in patients suffering from various forms of sickle cell disease with APM. Thus, Applicant's invention is not limited to treatment of only one particular disease such as arthritis but instead to treating whole blood viscosity associated with a variety of diseases. As amended, Claim 3 recites a method for treatment of high whole blood viscosity in a patient comprising the administration of an effective amount of a composition comprising APM or another alkyl ester wherein the effective amount causes a reduction in whole blood viscosity. As amended, Claim 12 recites a method for treating a patient having a disease characterized by abnormally viscous whole blood comprising administering in a treatment regimen to the patient an effective amount of a composition comprising APM or another aspartyl-phenylalanine alkyl ester wherein said effective amount causes a reduction in whole blood viscosity. Thus, a reduction in whole blood viscosity is an essential element in the claims as amended.

Applicant notes that the Examiner recognizes Edmundson et al. does not explicitly disclose treating for high whole blood viscosity or abnormally viscous whole blood in a patient. Edmundson et al. discloses a method of decreasing pain in a patient wherein the source of pain is associated with various conditions including osteoarthritis (Example 2), multiple sclerosis (Example 3), injury to tendons and ligaments of the foot (Example 4), back surgery (Example 5), and myocardial infarction (Example 6). Thus, Edmundson discloses decreasing pain in a patient wherein the source of pain is not necessarily associated in any way with a disease associated with high whole blood viscosity; therefore, a person skilled in the art would not anticipate a connection between treating pain and reducing whole blood viscosity with APM or another aspartyl-phenylalanine alkyl ester. Since Edmundson et al. does not teach or suggest a method of treating high whole blood viscosity in a patient or a method of treating a patient having a disease characterized by abnormally viscous whole blood comprising administering a composition comprising an effective amount of APM or another aspartyl-phenylalanine alkyl

ester to *cause a reduction in whole blood viscosity*, Edmundson et al. does not possess each and every element of the present claims.

For the foregoing reasons, Applicant believes that amended Claims 3 and 12 and Claims 4, 5 and 13-16 are not anticipated by Edmundson et al. and respectfully requests the rejection of these claims be withdrawn.

Applicant does not believe that a fee is required for this amendment. However, if this is error, please charge any necessary fee to Sidley Austin Brown & Wood LLP's Deposit Account No. 18-1260.

Respectfully submitted,

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